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Control of Measuring and Test Equipment and Calibration Standards OSTI-LLNL-QIP-12.0, Rev. 0, Mod 2

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Disclaimer

Auspices Statement

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LAWRENCE LIVERMORE
NATIONAL LABORATORY

CONTROL OF MEASURING AND TEST EQUIPMENT AND CALIBRATION STANDARDS

Quality Implementing Procedure ID: OSTI-LLNL-QIP-12.0, Rev. 0, Mod. 2 *Effective* 5/1/06

1. PURPOSE

This Quality Implementing Procedure (QIP) establishes the responsibilities and processes for the identification, calibration, control, storage, and maintenance of measuring and test equipment (M&TE) used for work scopes for the Office of Science & Technology and International (OSTI)-Lawrence Livermore National Laboratory (LLNL) Project.

2. APPLICABILITY

This QIP applies to the control of M&TE subject to the OSTI-LLNL Quality Assurance Plan (QAP), which implements the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, and shall be used to document and resolve conditions resulting from the identification, calibration, storage, use, out-of-calibration/tolerance conditions, loss, damage, and removal from service of M&TE. This procedure may also be used for activities not subject to the controls of the QAP. M&TE software that is developed or modified by the OSTI-LLNL Project shall be controlled in accordance with OSTI-LLNL-QIP-SI.0, *Software Management.*

This procedure does not apply to standard commercial equipment (e.g., rulers, tape measures, levels, and other commercial equipment) that provides adequate accuracy for the intended work, unless those devices are specifically identified as requiring calibration by the PI within controlled implementing documents, or where there are no specified, required tolerances or accuracies.

This QIP applies to the Deputy Project Manager (DPM), Principal Investigators (PIs) or Responsible Individuals, and the M&TE Coordinator within the OSTI-LLNL Project who control M&TE (including equipment that contains software or programmable hardware) and calibration standards. This procedure has been prepared in accordance with OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures.*

3. PROCEDURE

3.1 Identification and Listing of M&TE

3.1.1 PI (or Responsible Individual):

A. Select the appropriate M&TE for use based upon anticipated measurement range capabilities and environmental considerations under which the equipment will be expected to perform.

B. Ensure that M&TE is uniquely identified by tag, sticker, marking, or other means to maintain traceability to its calibration documentation.

C. Provide information on M&TE to the M&TE Coordinator, as listed in Section 3.1.2.

D. May use M&TE procured for the YMP that has been calibrated by a calibration service supplier listed on the DOE OCRWM Qualified Suppliers List (QSL) in accordance with the YMP or OSTI procurement processes.

3.1.2 M&TE Coordinator:

Maintain an up-to-date list of OSTI-LLNL M&TE that shall include the following, as a minimum:

A. Unique identification of the M&TE

B. Description or type of M&TE

C. Date calibrated

D. Recalibration due date or frequency of calibration or shelf life, as appropriate

E. Required calibration tolerance or a reference to same, where applicable

F. Non-retrievability status (e.g., Non-retrievabile (NR) or Retrievable (R)).

Additional (optional) information may be added to the M&TE List and updated at the discretion of the M&TE Coordinator.

3.2 Establishment of Standards for Internal Calibration

The PI (or Responsible Individual) shall:

A. Obtain M&TE calibration standards having traceability to nationally recognized standards (e.g., standards from the National Institute of Standards and Technology [NIST]). If no nationally recognized standards or physical constants exist, document the basis for calibration on M&TE Justification Form, (Attachment 1) in accordance with instructions provided, or in a scientific notebook that includes, as a minimum, the information required by the M&TE Justification form.

B. Ensure that standards have accuracy greater than the required accuracy of the M&TE to be calibrated, except as follows:

- Use standards with an accuracy equal to that of the M&TE if use of these standards can be shown to adequately meet the requirements and if standards with a greater accuracy do not exist or are unavailable.
- Document the justification on the M&TE Justification form or in a scientific notebook that includes, as a minimum, the information required by the M&TE

Justification form by explaining why the accuracy is limited and why the accuracy is adequate for the M&TE's intended use.

C. Forward the M&TE Justification form to the M&TE Coordinator for updating the M&TE list, as applicable, and to the Records Coordinator for submittal to the Records Center (RC) in accordance with Section 4.0 of this procedure.

3.3 CALIBRATION OF M&TE

3.3.1 The **PI (or Responsible Individual)** shall ensure that:

A. M&TE is calibrated, adjusted, and maintained, as appropriate, at established intervals, or prior to use, against reference calibration standards having traceability to nationally recognized standards, either by a calibration service supplier on the DOE OCRWM Qualified Supplier List (QSL) or by a qualified OSTI-LLNL staff member.

B. Calibration of M&TE shall be documented either in a scientific notebook or using M&TE Calibration Documentation Form (Attachment 2) in accordance with the attached instructions. Calibration documentation shall include:

1. Unique identification of the M&TE calibrated.

2. Identification of and traceability to the calibration standard(s) used for calibration.

3. Calibration data.

4. Individual(s) performing the calibration.

5. Date of calibration and the recalibration due date or calibration interval/frequency, as appropriate.

6. Results of the calibration and statement of acceptability.

7. Reference to M&TE Out-of-Calibration Report (OCR) number, if generated as a result of calibration. For M&TE calibrated by a calibration service supplier, this reference can be made on the Acceptance Report for Calibration Services that is completed in accordance with OSTI-LLNL-QIP-7.0, *Control of Purchased Products and Services.*

8. Identification of the implementing document (including revision level) used in performing the calibration.

9. As-found condition of the M&TE, as appropriate.

10. Specified range and tolerances and whether the M&TE met those tolerances.

C. Forward the calibration documentation to the M&TE Coordinator for updating the M&TE List, as applicable.

D. M&TE identified as calibrated in the as-left condition from internal or service supplier calibration and whose as-found calibration was found to be out-of-tolerance, may be released for use provided an OCR has been initiated in accordance with Section 3.6 of this Procedure to evaluate the impact of the as-found out-of-tolerance condition on data collection, processes monitored or items evaluated while using the M&TE.

3.3.2 Procedures for Internal Calibration

The **PI (or Responsible Individual)** shall ensure that:

A. Technical Implementing Procedures (TIPs) are developed and maintained, per Item B below, for the calibration of M&TE in accordance with OSTI-LLNL-QIP-5.0. For one-time-only calibration, the calibration process may be documented in a scientific notebook in accordance with the requirements of OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks.*

B. Calibration procedures or process documentation addresses the following requirements for the equipment to be calibrated:

- Identification of standards to be used
- Detailed description of calibration method
- Identification of tolerances and range of use.

C. Ensure that pertinent information from equipment vendor manuals is incorporated into the applicable implementing document or that the manuals are controlled per OSTI-LLNL-QIP-6.0, *Controlled Documents.*

3.3.3 Calibration by a Service Supplier

The **PI (or Responsible Individual)** shall ensure that:

A. Procurement of calibration services is performed in accordance with OSTI-LLNL-QIP-4.0, *Procurement Document Control.* **Calibration services procured for the YMP will be acceptable for use on the OSTI-LLNL project provided the supplier is qualified in accordance with Section 3.3.3.B, below.**

B. The supplier is listed on the DOE OCRWM QSL. Should OSTI-LLNL require the use of a supplier not on the QSL, the QA Manager shall request OQA to perform a supplier audit.

C. Calibration documentation generated meets the requirements of Section 3.3.1, Item B, and is submitted to the M&TE Coordinator for updating the M&TE list, as applicable, and to the Records Coordinator for submittal to the RC in accordance with Section 4.0 of this procedure.

3.3.4 Tagging Equipment

The **PI (or Responsible Individual)** shall:

A. Attach an M&TE Calibration Sticker (see M&TE Calibration Sticker and Out of Service Tag Examples, Attachment 3) to M&TE if the calibration documentation is acceptable. The means of attachment shall not impair the function or accuracy of the equipment. If the device is too small to attach a calibration sticker, the sticker may be attached to the M&TE storage container as long as the container stays within proximity when the device is in use. Calibration stickers for calibrated M&TE that are not accessible for observation may be displayed in reasonable proximity to the device. M&TE that cannot be physically tagged and do not have containers may be referenced by their locations on grids, charts, or other documents.

B. Enter the following information on the M&TE Calibration Sticker:

- If the calibration was performed by a calibration service supplier, enter the name of the supplier and the initials of the person attaching the calibration sticker in the "BY" space, if not accomplished by the supplier.
- If the calibration was performed internally, enter the name or initials of the person performing the calibration in the "BY" space.
- Date calibrated. As a minimum, the calibration date should consist of month and year.
- Due date for the next calibration (month and year) if the device is placed in service.
- Unique identification number of the M&TE.

3.3.5 One-Time Use of M&TE

The **PI (or Responsible Individual)** shall:

A. Ensure that M&TE used in a one-time only application is calibrated both before and after use.

B. Document on the M&TE Justification form (Attachment 1) or in a scientific notebook that includes, as a minimum, the information required by the M&TE Justification form, the justification for validity of data collected during activities that prevent operational checks, or recalibration of the data collection equipment during or after its use (e.g., Nonretrievable M&TE).

C. Submit a copy of the justification to the M&TE Coordinator for updating the M&TE list, as applicable, and to the Records Coordinator for submittal to the RC in accordance with Section 4.0 of this procedure.

3.4 STORAGE OF M&TE

The **PI (or Responsible Individual)** shall ensure that:

A. M&TE, when placed in storage, are appropriately stored, handled, and protected to maintain accuracy and to reduce the likelihood of damage or loss. Consider the manufacturer's recommendations regarding storage and handling.

B. Access to designated M&TE storage is adequately controlled. Methods may include locked cabinets, rooms, buildings, or other appropriate means.

3.5 USAGE OF M&TE

3.5.1 The PI (or Responsible Individual) shall:

A. Document the use of M&TE, so that if the calibration validity of the M&TE comes under question, items, equipment, devices, data, and products associated with the M&TE can be identified, rechecked, or re-evaluated. Use of M&TE shall be documented on the M&TE Standards Usage Log (Attachment 4) or in a scientific notebook or by other means (e.g., documents generated by TIPs). Include, as applicable, the date the M&TE entered service, the individual who placed the instrument into service, a reference to the equipment tested or a reference to the form used for the test, and the date the M&TE or standard was removed from service.

B. Perform an operational check or recalibrate the M&TE when its accuracy is suspect (i.e., conditions exist that could be expected to have changed the M&TE calibration, or the M&TE is sensitive to motion and the instrument has been moved).

C. Document the check and/or recalibration results in accordance with controlled implementing procedures or method documented in a scientific notebook.

D. Forward the documentation to the M&TE Coordinator for updating the M&TE list, as applicable, and to the Records Coordinator for submittal to the RC, in accordance with Section 4.0 of this procedure.

3.6 OUT-OF-CALIBRATION CONDITIONS

3.6.1 PI (or Responsible Individual):

A. Consider M&TE to be out of tolerance or out of calibration if any of these conditions exist, as applicable:

1. The calibration due date or interval has passed without recalibration when M&TE is in use.

2. The M&TE produces results known to be in error.

3. Software or programmable hardware for the M&TE has been upgraded and affects calibration.

4. M&TE that has not been calibrated has been used to collect data or gauge performance.

5. The M&TE has been subjected to recalibration procedures or periodic checks and found to be out of the allowed specification tolerances.

B. Control out-of-calibration M&TE to prevent inadvertent use by doing one or more of the following:

1. Apply an M&TE Out of Service tag (Attachment 3) to the M&TE to indicate the out-of-calibration condition and that the M&TE is not to be used. Tags indicating an out-of-calibration condition shall include, as a minimum:

- Description of the M&TE
- Unique identifier of the M&TE
- Reason for applying the tag and any comments thereof.
- Dated signature of person tagging the M&TE

2. Segregate the out-of-calibration M&TE by removing the M&TE to an area identified as "segregated" or "out-of-service."

C. Document the out-of-calibration conditions of M&TE on the M&TE Out of Calibration Report (OCR) (Attachment 5) in accordance with the instructions provided.

D. Forward OCR information to the M&TE Coordinator.

3.6.2 The **M&TE Coordinator** shall control the issuance of M&TE OCR numbers by:

A. Maintaining a log of the issuance of OSTI-LLNL M&TE OCRs.

B. Ensuring numbers conform to the following format: OSTI-LLNL-OCR-YYYY-NNN, where:

- YYYY represents the Fiscal Year M&TE OCR was initiated
- NNN represents a unique number, starting with 001, for the first report of the Fiscal Year and using sequential numbers thereafter.

3.6.3 The **PI** shall ensure that technical staff (if not the PI) knowledgeable in the functional use of the M&TE and its relation to the data collected evaluates the impact to the data.

3.6.4 The **PI (or Responsible Individual)** shall evaluate the impact to data collection, process monitored, or items evaluated as a result of using out-of-calibration M&TE.

A. If it is determined that there is an impact, immediately report the condition on a nonconformance report (NCR) in accordance with OSTI-LLNL-QIP-15.0, *Nonconformances*, and note the NCR number on the M&TE OCR.

B. If it is determined that there is no impact, document the justification for this decision on the M&TE OCR. This evaluation and justification shall be sufficiently supported by a logical, documented process to address applicable issues such as reviews of previously collected data, calibration history for the specific M&TE, statistical analysis and comparisons, and the operational status up to the point of the out-of-calibration condition.

C. Submit the M&TE OCR for review and concurrence to the PI (or Deputy PM if PI is the OCR Initiator) if M&TE are found to be out of the specified tolerance.

3.6.5 The **PI (or Deputy PM)** shall review the M&TE OCR and complete Block 14 if it is satisfactory, or return it to the OCR Initiator if it is unsatisfactory.

3.6.6 PI (or Responsible Individual):

A. Forward the completed M&TE OCR to the M&TE Coordinator for updating the M&TE list, as applicable, and to the Records Coordinator for submittal to the RPC in accordance with Section 4.0 of this procedure.

B. Repair or replace M&TE that is consistently found to be out of calibration when recalibrated.

3.7 LOSS OF OR DAMAGE TO M&TE

3.7.1 The PI (or Responsible Individual) shall:

A. Document the loss of or damage to M&TE, if it has been used since its last valid calibration, on an M&TE OCR in accordance with the instructions provided.

B. Submit a copy of the documentation of loss or damage to the M&TE Coordinator.

C. Evaluate the impact to data, processes monitored, items previously inspected, or results obtained from M&TE that is lost or damaged.

D. Affix a tag to the damaged M&TE and segregate it from undamaged M&TE to indicate that it is not to be used and is out of service.

E. Submit the M&TE OCR for review and concurrence to the PI or the Deputy PM, as appropriate.

3.7.2 The PI (or Deputy PM if PI is the OCR Initiator) shall review the M&TE OCR and complete Block 14 if it is satisfactory, or return it to the OCR Initiator if it is unsatisfactory.

3.7.3 PI (or Responsible Individual):

A. Forward the completed M&TE OCR to the M&TE Coordinator for updating the M&TE list, as applicable, and to the Records Coordinator for submittal to the RC in accordance with Section 4.0 of this procedure.

B. Repair or replace M&TE that is consistently found to be out of calibration when recalibrated.

3.8 REMOVAL OF M&TE FROM SERVICE

PI (or Responsible Individual), when M&TE is to be removed from service:

A. Perform a calibration of the M&TE, if operable, to ensure the M&TE remained within calibration tolerances since its last calibration and document the calibration in accordance with controlled implementing procedures.

B. If the M&TE is found to be out of calibration or damaged, refer to Section 3.6 or 3.7, as applicable.

4. RECORDS

The documents listed in Sections 4.1 and 4.2 shall be collected and submitted to the Records Coordinator for submittal to the RC in accordance with OSTI-LLNL-QIP-17.0, *Records Management*, as individual records or included in a records package, as specified. If these Records are incorporated into a Scientific Notebook, they shall be submitted to the RC as part of the Scientific Notebook Records Package. The records listed in Section 4.3 shall be maintained by OSTI-LLNL as directed by the PI.

4.1 QA Records

Submit as an Individual Record or a Records Package, as applicable:

Measuring and Test Equipment Justification form

M&TE Calibration Documentation Form (part of a Records Package)

Measuring and Test Equipment Out of Calibration Report

Measuring and Test Equipment Standards Usage Log

4.2 Non-QA Long-Term Records

Submit as an Individual Record or a Records Package, as applicable:

Measuring and Test Equipment Justification form

M&TE Calibration Documentation Form (part of a Records Package)

Measuring and Test Equipment Out of Calibration Report

Measuring and Test Equipment Standards Usage Log

4.3 Non-QA Short-Term Records (three years or less retention)

M&TE list

5. RESPONSIBILITIES

5.1 The **Deputy Project Manager** (PM) is responsible for review and approval of OCRs if the PI is the initiator of the OCR.

5.2 The **PI (or Responsible Individual)** is responsible for obtaining, uniquely identifying, storing, using, and maintaining M&TE in accordance with manufacturers specifications; obtaining or creating M&TE calibration standards; obtaining calibration of M&TE from suppliers or performing internal calibrations of M&TE, as needed; identifying, segregating, and documenting out-of calibration equipment, and evaluating the impact of out-of-calibration conditions, and ensuring NCR's are initiated if appropriate. The PI (or Responsible Individual) is also responsible for attaching stickers identifying M&TE and calibration due dates for internal calibrations. The **PI** is responsible for the review and approval of OCRs.

5.3 The **M&TE Coordinator** is responsible for creating and maintaining an up-to-date list of M&TE, for purposes of identifying M&TE, tracking usage and calibrations of M&TE, and documenting and issuing numbers for out-of-calibration reports (OCRs).

6. ACRONYMS AND DEFINITIONS

6.1 ACRONYMS

DOE	U.S. Department of Energy
LLNL	Lawrence Livermore National Laboratory
M&TE	Measuring and test equipment
NCR	Nonconformance Report
NIST	National Institute of Standards and Technology
NR	Non-retrievable
OCR	Out of Calibration Report
OCRWM	Office of Civilian Radioactive Waste Management
OSTI	Office of Science & Technology and International
PI	Principal Investigator
QA	Quality assurance
QAP	Quality Assurance Plan
QARD	Quality Assurance Requirements and Description
QIP	Quality Implementing Procedure
QSL	Qualified Suppliers List

R	Retrievable
RC	Records Center
TIP	Technical Implementing Procedure

6.2 DEFINITIONS

Accuracy: The degree of agreement of the measurement with the true value of the quantity measured.

Calibration: The comparison of a measurement standard or instrument of known accuracy with another standard or instrument to detect, correlate, report, or eliminate by adjustment any variation in the accuracy of the instrument or equipment being compared.

Calibration Standard: A reference used in measurement or test comparisons with working M&TE.

Measuring and Test Equipment: Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements (QARD).

Non-retrievable M&TE: M&TE that is installed in situ and cannot be, or is not intended to be, retrieved for recalibration.

Operational Check: An examination performed and documented to verify that M&TE is functioning and operating within specified tolerances.

Out of Calibration: An all-inclusive term that identifies M&TE that has never been calibrated, has not been recalibrated within the required time period, has been subjected to recalibration procedures or periodic checks and found to be out of the allowed specification tolerances (i.e., out of tolerance), or has been damaged, lost or found in a condition that has been determined to be suspect.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LLNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LLNL-QIP-6.0, *Controlled Documents*

OSTI-LLNL-QIP-7.0, *Control of Purchased Products and Services*

OSTI-LLNL-QIP-15.0, *Nonconformances*

OSTI-LLNL-QIP-17.0, *Records Management*

OSTI-LLNL-QIP-18.0, *Quality Assurance Audits and Management Assessments*

OSTI-LLNL-QIP-SI.0, *Software Management*

OSTI-LLNL-QIP-SIII.0, *Scientific Notebooks*

8. ATTACHMENTS

Attachment 1 - Measuring and Test Equipment Justification

Attachment 2 – M&TE Calibration Documentation Form

Attachment 3 - M&TE Calibration Sticker and Out of Service Tag Examples

Attachment 4 - Measuring and Test Equipment Standards Usage Log

Attachment 5 - Measuring and Test Equipment Out of Calibration Report

9. REVISION HISTORY

2/25/05 Revision 0, Modification 0
Initial Issue

10/14/05 Revision 0, Modification 1
Page 3, Subsection 3.3.1.B; Attachment 2: Revised calibration documentation to be consistent with the latest revision of LP-12.1Q-BSC in accordance with corrective action per CR5792. Page 11, Section 7: added reference to QIP 7.0 since it is referenced in revised Subsection 3.3.1.B. Page 1, Sections 1.0 & 2.0; Page 3, Subsection 3.3.1.A; Page 4, Subsections 3.3.1.D & 3.3.3.B; Page 5, Subsection 3.3.4.B; Page 9, Subsections 4.1 & 4.2; Page 10, Subsection 5.2; Attachment 2; Attachment 5, Instructions: editorial changes and clarifications.

5/1/06 **Revision 0, Modification 2**
Page 2, added Subsection 3.1.1.D and Page 4, modified Subsection 3.3.3.A to allow the use of M&TE and calibration service suppliers procured for the YMP on the OSTI-LLNL Project.

10. APPROVALS

Preparer: Leigh A. Gouveia — Date: 4/19/06

Technical Reviewer: Qinhong Hu — Date: 4/27/06

QA Reviewer: Victor J. Barish, Jr. — Date: 4/20/06

Project Manager: James A. Blink — Date: 1 May 06

1. QA:

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Page ____ of

MEASURING AND TEST EQUIPMENT JUSTIFICATION

2. M&TE ID No.: _____ 3. M&TE Type: _____

4. Initiator Name: _____ 5. Date: _____

6. Principal Investigator or Responsible Individual _____

7. Justification:

8. Approved By:

Principal/ Responsible Individual _____
Printed Name

9. _____
Date:

_____
Signature

MEASURING AND TEST EQUIPMENT JUSTIFICATION FORM INSTRUCTIONS

PI (or Responsible Individual):

1. Enter the QA designation and enter the number of pages
2. Enter unique M&TE identification number. If the justification is for a particular type of M&TE and not for a specific device, enter "N/A" in this block.
3. Enter type or description of M&TE.
4. Print name of person initiating the justification form.
5. Print date when justification form is initiated.
6. Print name of PI (or Responsible Individual)
7. Enter appropriate justification.

PI (or PM/DPM), after the justification has been reviewed and approved:

8. Print and sign name in the spaces provided.
9. Print date in space provided.

Measuring and Test Equipment (M&TE) Calibration Documentation

1. M&TE Description	**2. M&TE Unique Identification**	**3. Calibration Date and Time (if applicable)**
4. Person Performing Calibrations		**5. M&TE Condition (As-Found)** Working _____ Not Working _____
6. Calibration Procedure (including revision level)		**7. Calibration Standards Used**
8. Location of Calibration Data		**9. Location of Calibration Results**
10. Specified Range of Use and Tolerances		
11. Statement of Acceptability including Acceptability of Range and Tolerances Range Acceptable Yes _____ No _____ Tolerance Acceptable Yes _____ No _____ Calibration Acceptable Yes _____ No _____ Comment:		
12. Re-calibration due date or calibration interval/frequency		**13. Reference to OCR Number, including evaluation results, as appropriate** OCR Number: _____
14. Comments		

Signature Date

M&TE Out of Service Tag Examples

Description:

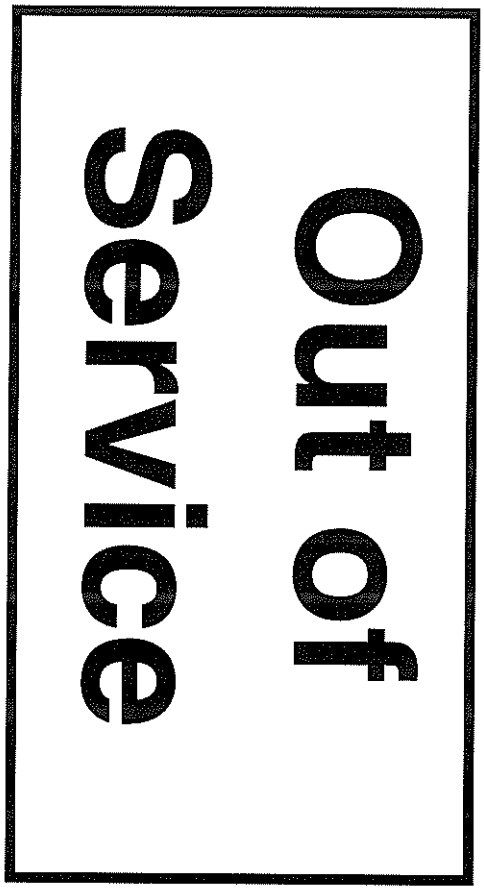
ID #:

- **Calibration Required**
- **Damaged**
- **Maintenance Required**

Comments/Disposition

Signature **Date**

(Front)



(Back)

M&TE Calibration Sticker

CALIBRATION	
BY	DATE
NEXT CAL DUE	
INSTRUMENT #	

OSTI-LLNL
MEASURING AND TEST EQUIPMENT
STANDARDS USAGE LOG

QA:

Page 1 of :

M&TE ID No. :	S/N:			Description:		
OUT		IN				
Date	PI or Responsible Individual	Date	PI or Responsible Individual	Location Used	Equipment	Damage/Comments

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MEASURING AND TEST EQUIPMENT
OUT OF CALIBRATION REPORT

1. QA:

Page ____ of ____

2. M&TE OCR No:

3. Initiator Name: | 4. Date: | 5. Principal Investigator or Responsible Individual

6. M&TE/Operating Equipment Description:

7. ☐ Q ☐ non-Q 8. M&TE No.: | 9. Last Calibration Date or In Service Date:

10. Out of Calibration Condition | 11. ☐ Out of Service Tag Affixed

12. ☐ Continuation Page

13. Condition Impact Evaluation:

14. ☐ NCR NCR No.: | 15. ☐ Continuation Page

16. Performed by: Date

17. Equipment Disposition Recommendation:

18. Name Date

19. Name Date

20. Completion of Equipment Disposition: | Date:

21. Final Approval and Close Out: PI or Responsible Individual

Printed Name	Signature	Date

MEASURING AND TEST EQUIPMENT OUT OF CALIBRATION REPORT INSTRUCTIONS

Initiator (Items 1–12)**:**

1. Enter the QA designation and enter the number of pages.

2. Enter unique M&TE OCR organization sequential tracking number (obtained from M&TE Coordinator).

3. Print Initiator Name.

4. Print Date.

5. Identify the Principal Investigator (PI) (or Responsible Individual) who is responsible for the care and maintenance of the M&TE identified as being out of calibration.

6. Identify the M&TE by entering the name of the equipment and any other appropriate identifying information, as applicable.

7. Identify the use of the M&TE as Quality Affecting (Q) or non-Quality Affecting (non-Q) by checking the appropriate box.

8. Enter the M&TE unique identification number.

9. Identify the date the instrument or equipment was last calibrated.

10. Describe the present condition of the equipment. If needed to accurately describe the condition, include the location of the M&TE when identified as being out of calibration, the function and use of the equipment, and the job scope or activity for which the equipment is used.

11. Check if Out of Service tags are affixed to the equipment to identify that the equipment cannot be used. Once this has been done, the equipment is to be segregated to prevent inadvertent use, as practicable.

12. Check the Continuation Page box if additional pages are required to provide a description of the equipment. If a Continuation Page is used, it should contain, as a minimum, the M&TE OCR number and the Item No. 12.

PI (or Responsible Individual) knowledgeable in the functional use of the M&TE and its relationship to the data collected (Items 13–18)**:**

13. Prepare the Condition Impact Evaluation, evaluating the effect to preliminary data and the validity of results. Provide documented justification when evaluation conclusions indicate no impact to data.

14. Initiate an NCR, as prescribed in OSTI-LLNL-QIP-15.0, if out-of-calibration conditions are found to have impacted products. Check the NCR box and insert the NCR Number, as issued from the Office of Quality Assurance.

15. Check the Continuation Page box if additional pages are required. If a Continuation Page is used, it should contain, as a minimum, the M&TE OCR number and the Item No. 15.

.16. Sign and date in the spaces provided.

17. Identify the disposition of the out-of-calibration M&TE (i.e., send to the vendor or manufacturer for repair and recalibration, scrap, replacement, etc.).

18. Sign and date the disposition and present the recommendation to the PI (if performed by the Responsible Individual) or PM/DPM (if performed by the PI), for approval.

PI or PM/DPM:

19. Evaluate the Condition Impact Evaluation and the Equipment Disposition Recommendation and either approve or reject them. Should the evaluation and/or recommendation be rejected, the OCR will be returned to the designated individual for re-evaluation.

PI (or Responsible Individual) :

20. Upon completion of the disposition, enter date of completion.

PI or PM/DPM:

21. Review the actions and completion date and, if all actions are completed, print and sign name and date in the appropriate spaces to close the actions and return the M&TE to service.